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X-RAY EMITTING SYSTEM AND METHOD

BY

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TECHNICAL FIELD OF THE INVENTION

The present invention relates to a system and method for emitting x-rays, and more specifically, the invention relates to a system and method for administering a desired x-ray dose from an x-ray device.

BACKGROUND OF THE INVENTION

X-ray emitters such as x-ray catheters typically consist of an anode and cathode assembly mounted in a miniature vacuum tube. During operation, a high DC voltage (15 to 35 kV) is applied to the assembly from a power source. A high electrical field in the anode-to-cathode gaps causes an electron field emission from the cathode surface. The electrons, emitted into the vacuum gap, are accelerated by the electrical field and strike the anode, radiating x-ray energy as they are stopped.

The emission properties of a thermionic cathode, or hot cathode, depend on the temperature of the cathode surface. A hot cathode utilizes an additional electrode providing a low voltage current for heating the cathode surface. The emission properties and the current at the anode are improved by elevating the cathode surface temperature. Furthermore, the anode current and voltage can be controlled and stabilized independently from each other.

A field emission cathode, or cold cathode, may be preferred to a hot cathode in medical procedures and other applications. The cold cathode provides a smaller size and lower operating temperature due to the lack of the heating electrode. In a cold cathode, the value of the field emission current is exponential function of the applied voltage. Therefore, the cold cathode cannot provide independent control of the voltage and current.

X-ray catheters are utilized during medical procedures including percutaneous transluminal coronary angioplasty (PTCA) and when irradiation of vessels or body cavities is required. The successful operation of the x-ray catheter requires the ability to administer a precise radiation dose to a target area. The inherent instability of electron emission from cold cathodes provides a technical difficulty in designing power supplies for the catheters. Ideally, the voltage and current should be measured so that the irradiation dose can be calculated in real-time. The calculated dose could then be adjusted to correspond to a desired dose for the given application.

At least two strategies exist for measuring and controlling the irradiation dose emitted from x-ray devices including field emission cathodes. One method monitors and integrates current while voltage is stabilized. The total accumulated dose is calculated as proportional to the electric charge passed through the emitter. A narrow set of stabilized operating voltages (18 to 21 kV), however, is required to maintain the irradiation rate at a nominal value.

Another method utilizes high voltage pulses with stabilized amplitude. The U.S. Patent No. 6,069,938 issued May 30, 2000 to Chornenky *et al.* is an example of a method and x-ray device using a pulse high voltage source. In the Chornenky patent, current passing through the x-ray emitter is measured and integrated. Rectangular voltage pulses with stabilized amplitude and known cycle are applied to the emitter. The average electrical current is stabilized by changing the width of the pulses, thus stabilizing the irradiation rate and controlling dose. The technical difficulty of switching high voltage power up and down is not desirable from a manufacturing and cost viewpoint.

The disclosed and other strategies may provide a stable and controlled irradiation dose rate. The current designs, however, have limitations including large unit size and cost, heat generation, and narrow operating voltage range. Therefore, it would be desirable to achieve an x-ray device with a stabilized irradiation rate that overcomes the aforementioned and other disadvantages.

SUMMARY OF THE INVENTION

One aspect of the invention provides a system for emitting x-rays comprising: an x-ray emitter, a controller operably connected to the x-ray emitter, a current sensor operably connected to the controller, and a voltage sensor operably connected to the controller. The controller may determine an actual dose rate based on a received current sensor signal and a received voltage sensor signal and may adjust a supplied voltage to allow the actual dose rate to match a predetermined dose rate. The current and voltage sensors measure the current and voltage, respectively, through the x-ray emitter a plurality of times per second. The controller may adjust the actual dose rate based on an irradiation depth by correcting for tissue radiation absorption and an increased radial target area with increasing treatment radius. The controller may further comprise a current integrator operably connected to the current sensor and the controller to integrate instant current values over time to determine an accumulated charge. The actual dose rate may be calculated a plurality of times per second and may be determined according to: $D = f \times I \times (V-V_0)^2$ wherein D is the actual dose rate at a distance r from the emitter, f is a constant, I is a current through the x-ray emitter, V is a voltage applied across an anode and a cathode, and V_0 is a constant.

Another aspect of the invention provides for a method of operating a device for emitting x-rays comprising: applying a voltage from a voltage source to the device, measuring current and voltage within the device, determining an actual dose rate based on the measured current and voltage, comparing a desired dose rate to the actual dose rate, adjusting the applied voltage, and matching the actual dose rate to the desired dose rate. The adjusting of the applied voltage may comprise stabilizing the actual dose rate; an operator may select the desired dose rate.

Yet another aspect of the invention provides for a computer usable medium storing a program for: determining an actual dose rate based on the measured current and voltage, comparing a desired dose rate to the actual dose rate, adjusting the applied voltage, and matching the actual dose rate to the desired dose rate.

The foregoing and other features and advantages of the invention will become further apparent from the following detailed description of the presently preferred embodiments, read in conjunction with the accompanying drawings. The detailed description and drawings are merely illustrative of the invention rather than limiting, the scope of the invention being defined by the appended claims and equivalents thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic overview of one embodiment of the present invention; and

FIG. 2 is a schematic diagram showing an actual dose rate as a function of time in another embodiment of the present invention.

DETAILED DESCRIPTION OF THE
PRESENTLY PREFERRED EMBODIMENT

A schematic overview of one embodiment of the invention is shown in **FIG. 1**. The x-ray system **10** comprises: an x-ray emitter **21**, a programmable controller **25** operably connected to the x-ray emitter **21**, a current sensor **28** operably connected to the programmable controller **25**, and a voltage sensor **27** operably connected to the programmable controller **25**.

Another embodiment of the invention provides for a method of operating a device for emitting x-rays, such as an x-ray emitter **21**, comprising: applying a voltage from a voltage source to the device, measuring current and voltage within the device, determining an actual dose rate based on the measured current and voltage, comparing a desired dose rate to the actual dose rate, adjusting the applied voltage, and matching the actual dose rate to the desired dose rate. The

configuration and operation of the aforementioned system and method may be further understood by the following description of the use of the embodiment.

The x-ray emitter **21** of the present invention may be a field emission diode including an anode and a cathode arranged within a vacuum housing to produce x-ray radiation. The cathode may include a thin diamond film, and may include a getter material that is activated to improve the quality of the vacuum within the housing, as described is U.S. patent application Ser. No. 08/806,244, which is incorporated by reference herein. Examples of suitable x-ray emitters of this application, components of the emitter, and various delivery systems for positioning such a catheter in a passage within a patient's body have been described in other patents. X-ray emitters are disclosed in U.S. patent No. 6,108,402 issued August 22, 2000 to Chornenky and U.S. patent No. 6,095,966 issued to Chornenky *et al.* and are incorporated by reference herein. Several examples of delivery devices, systems and methods that may be used with an x-ray emitter are described in U.S. patent No. 6,210,312 issued April 3, 2001 to Nagy and U.S. patent No. 6,183,410 issued February 6, 2001 to Jacobsen *et al.*, and are incorporated by reference herein.

The x-ray emitter **21** is schematically shown in **FIG. 1** at a position inside a patient's body. One skilled in the art can recognize that the x-ray emitter **21** may be utilized in a wide spectrum of medical and technical applications and is not limited to use in a human body. The x-ray emitter **21** may be connected to the programmable controller **25** via a cable **23** and situated within a sheath **22** lumen. The x-ray emitter 21 and cable **23** may be inserted into the patient's body via a suitable blood vessel and advanced through the vessel to the desired treatment area.

The voltage sensor **27** and the current sensor **28** may be connected to the high voltage power source **26** and the cable **23**. The cable **23** may be connected to a high voltage power source **26**. Those skilled in the art will appreciate that many different high voltage power sources may be used with the present invention. In one embodiment, the high voltage power source **26** supplies a voltage ranging from about 15 to 35 kV and current ranging from about 10 to100

microamperes to the x-ray emitter **21**. The voltage sensor **27** may be used to measure a voltage through the x-ray emitter **21** a plurality of times per second. The current sensor **28** may be used to measure a current through the x-ray emitter **21** a plurality of times per second. Many well-known voltage and current sensors may be used with this embodiment. For example, a voltmeter may be used to measure the voltage and an amperemeter may be used to measure the current. In one embodiment, the voltage sensor **27** and the current sensor **28** may perform their respective measurements about every 10 to 100 milliseconds. Additionally, the x-ray system **10** and method may include a current integrator **29** operably connected to the current sensor **28** and the programmable controller **25** to integrate instant current values over time to determine an accumulated charge.

The x-ray system **10** and method may further include a catheter pull-back assembly **24**. The catheter pull-back assembly **24** may include a body with a carriage slidably mounted on it. The sheath **22** may be connected to the body and the cable **23** may be connected to the carriage. By sliding the carriage on the body of the catheter pull-back assembly **24**, the cable **23** may be retracted within the sheath **22**, thereby moving the x-ray emitter **21**. The catheter pull-back assembly **24** may further include means for actuating the carriage from a distance. For example, an actuating cable may be connected to the carriage so that the carriage can be actuated by a control means, such as electro motor **30** separate from the catheter pull-back assembly **24**. The catheter movement may also be controlled by hand.

The programmable controller **25** may be connected to the high voltage power source **26** and ultimately may determine the supplied voltage to the x-ray emitter **21**. The programmable controller **25** may include different configurations of microprocessor(s), circuit board(s), component(s), and input and output devices depending on the particular intended use of the invention. The programmable controller **25** may run an algorithm in the form of a computer program to control components of the x-ray system **10** and method including the high voltage power source **26**. The computer program may determine an actual dose rate based on the measured current and voltage, compare a desired dose

rate to the actual dose rate, adjust the applied voltage, and match the actual dose rate to the desired dose rate.

The programmable controller **25** may be connected to the voltage sensor **27** and the current sensor **28** and may be connected to the current integrator **29** and the catheter pull-back assembly **24**. In one embodiment, an electrical or digital connection may be made between the device and the programmable controller **25** to provide for a sharing of measurements. In one embodiment, a mechanical connection, such as an actuator cable from the catheter pull-back assembly **24** to the programmable controller **25**, may be made to control movement of the x-ray emitter **21** via the catheter pull-back assembly **24**.

The programmable controller **25** may determine an actual x-ray dose rate based on a received current sensor **28** signal and a received voltage sensor **27** signal. The programmable controller **25** may adjust a supplied voltage to allow the actual dose rate to match a predetermined dose rate. Alternatively, the programmable controller **25** may determine the actual dose rate based on received current integrator **29** information, for example, the accumulated charge. The programmable controller **25** may adjust the actual dose rate based on an irradiation depth by correcting for tissue radiation absorption and an increased radial target area with increasing treatment radius. An operator, such as a physician performing the x-ray irradiation procedure, may select the predetermined dose rate and a total predetermined dose.

In one embodiment, the actual dose rate may be calculated based on a formula: $D = f \times I \times (V-V_0)^2$ wherein D is the actual dose rate at an irradiation depth, r, from the x-ray emitter **21**, f is a constant independent of current or voltage, I is a current through the x-ray emitter **21**, V is a voltage applied across an anode and a cathode, and V_0 is a constant. The constant, f, describes the absorption of x-ray radiation and the spread of the radiation over a larger cylindrical target area as the depth into tissue increases. In one embodiment, the constant, f, depends only on the irradiation depth, r. The irradiation depth, r, may depend on vessel wall x-ray absorption and increased radial target area with increasing treatment radius. The actual dose rate may be calculated or

measured experimentally and tabulated. This tabulation, for example, may provide an operator of the x-ray system **10** with the dose rate for given values of the current, I, voltage, V, and irradiation depth, r. V_0 is a constant that depends on the design of the x-ray emitter **21** and represents a cut-off energy of the x-ray radiation that is filtered out by the emitter shell and, thus, does not reach the target area. The programmable controller **25** may adjust the actual dose rate based on the irradiation depth, r, and the cut-off energy, V_0, determined by the spectrum of the emitted radiation. Theoretical simulations have shown that for Bremsstrahlung radiation the dose rate at the irradiation depth, r, from the x-ray emitter **21** can be described using the formula. For any x-ray emitter, the values, f and V_0, vary somewhat depending on the actual thickness of the emitter wall and the metal coating on the outside surface of the emitter. In one embodiment, a practical and precise way to measure the values, f and V_0, involves measuring the actual dose rate, D, at several different operating voltages. A curve fitting algorithm is then applies the data points to the formula $D = f \times I \times (V-V_0)^2$ to experimentally determine f and V_0.

The actual dose rate may be calculated a plurality of times per second. Ideally, the programmable controller **25** may perform the calculation about every 10 to 100 milliseconds. The calculation may involve utilizing information from the current sensor **28**, the current integrator **29**, the voltage sensor **27**, or combinations thereof. Furthermore, those skilled in the art will appreciate that any number of alternative formulae or approximative methods may effectively utilize the sensor(s) signal information to determine the actual dose rate. The programmable controller **25** then compares the calculated actual dose rate to the predetermined dose rate and adjusts the applied voltage to the x-ray emitter **21** thereby stabilizing the actual dose rate. For example, if the actual dose rate is above the predetermined dose rate, the voltage provided to the x-ray emitter **21** is lowered accordingly to match the actual dose rate to the predetermined dose rate. The process is shown in **FIG. 2**. Instabilities of the actual dose rate that may result in actual dose rate maxima **31**, D_{max}, and minima **32**, D_{min}, are balanced by the programmable controller. As a result, a mean value of the

actual dose rate approximately matches the predetermined dose rate **33** and a stabilized dose rate is achieved. Furthermore, the use of both current and voltage values to approximate the actual dose rate may provide an ability to administer a precise total radiation dose to a target area and may overcome an inherent instability of electron emission from cold cathodes.

In one embodiment, the x-ray emitter **21** may be positioned in a passage in a patient's body according to known procedures for catheterization. The x-ray emitter **21** may be positioned near a particular area that is to be treated with radiation. For example, the x-ray emitter **21** may be positioned near a particular treatment area such that it may be successively withdrawn during the treatment to deliver radiation to the entire treatment area. The x-ray emitter **21** may be delivered by connecting to the cable **23** and advancing the cable **23** through the sheath **22** that has been introduced into the passage. Furthermore, the sheath **22** may be advanced into the passage using a guide wire (not shown) by first introducing the guide wire into the passage and then advancing the sheath **22** along the guide wire.

X-ray radiation in the range of about 10 to 50 Grays may be applied to an area of the interior of a passage during treatment, for example, to prevent restenosis. Preferably, x-ray radiation in the range of 15 to 30 Grays may be applied to an interior body site. The treatment may be structured to last about 2 to 10 minutes. In one embodiment, the treatment may be structured to last about 3 to 5 minutes. The x-ray emitter **21** may be repositioned during the treatment course, depending on the length of the area requiring treatment.

In one embodiment, any particular treatment parameters for the patient may be entered into the programmable controller **25**. For example, the operating voltage, the length of the treatment area, and the desired dose rate may be entered as treatment parameters. The operating voltage determines the depth of x-ray penetration. The actual dose rate may depend on the surrounding tissue and the medical condition to be treated. When the x-ray emitter **21** is in its initial position and the treatment parameters have been entered the treatment may begin. High voltage may be supplied to the x-ray emitter and x-ray radiation is